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5.0 510(k) Summary

NOV - 1 2007

1. Sponsor

SpineFrontier, Inc.
100 Cummings Center
Suite 240C
Beverly, MA 01915

Primary Contact: Mr. Thomas A. Carlson
Telephone: 1-978-232-3990

Date Prepared: October 16, 2007

2. Device Name:

Proprietary Name:	***DORADO™ Intervertebral Body Cage***
Common/Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification Name:	Intervertebral Fusion Device With Bone Graft, Lumbar (21 CFR 888.3080), Class II, Product Code MAX

3. Predicate Device(s)

P960025 – Saber Lumbar I/F Cage and Jaguar Lumbar I/F Cage
P950002 – BAK Interbody Fusion System with Instrumentation

4. Device Description

The ***DORADO™ Intervertebral Body Cage*** is a spinal intervertebral body cage intended for a posterior approach and uses autogenous bone graft in patients with degenerative disc disease (DDD) at one or two spinal levels from L2-S1. The system is comprised of devices of various fixed heights and footprints to fit the anatomical needs of a wide variety of patients. The device has raised contours on the superior and inferior surfaces that will resist implant pullout.

5. Intended Use

The ***DORADO™ Intervertebral Body Cage*** is a spinal intervertebral body cage intended for a posterior approach and uses autogenous bone graft in patients with degenerative disc disease (DDD) at one or two spinal levels from L2-S1. These DDD patients may also have up to Grade I

spondylolisthesis or retrolithesis at the involved level(s). The SpineFrontier ***DORADO™ Intervertebral Body Cage*** is intended to be used with supplemental spinal fixation system(s) (Example: Posterior Pedicle Screw).

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

6. Technological Characteristics and Substantial Equivalent

The SpineFrontier ***DORADO™ Intervertebral Body Cage*** and its predicate device have the same indications for use and operating principles.

Representative samples of the device were tested according to ASTM standards to demonstrate comparable functional and performance characteristics to the predicate device. The 17mmx25mm device was selected for testing to support the addition of the 17mm device. Although the ***DORADO™*** cage (Peek Optima®-LT1 ®) and predicate (CFR-Peek Optima®) materials vary slightly in content, the results of the ASTM mechanical testing demonstrate substantial equivalence.

7. Performance Testing

The testing method for the ***DORADO™ Intervertebral Body Cage*** followed ASTM F2077-03, "Test Methods for Intervertebral Body Fusion Devices," ASTM F2267-04, "Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression," and ASTM Draft Standard F-04.25.02.02, "Static Push-out Test Methods for Intervertebral Body Fusion Devices." Draft #2 – August 29, 2000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2007

SpineFrontier, Incorporated
c/o Mr. Tom Carlson
Chief Operating Officer
100 Cummings Center, Suite 240C
Beverly, MA 01915

Re: K072289
Trade/Device Name: Dorado™ Intervertebral Body Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: October 16, 2007
Received: October 17, 2007

Dear Mr. Carlson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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4.0 Indications for Use Statement

510(k) Number (if Known): K072289

Indications for Use:

The ***DORADO™ Intervertebral Body Cage*** is a spinal intervertebral body cage intended for a posterior approach and uses autogenous bone graft in patients with degenerative disc disease (DDD) at one or two spinal levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolithesis at the involved level(s). The SpineFrontier ***DORADO™ Intervertebral Body Cage*** is intended to be used with supplemental spinal fixation system(s) (Example: Posterior Pedicle Screw).

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Prescription Use: X **AND/OR** **Over-The-Counter Use:** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 807 Subpart C)**

Mark A Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072289